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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,186	02/08/2002	Joel Richard	03715.0109	8142

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EXAMINER
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KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/25/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/049,186

Applicant(s)

Richard

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

**The preliminary amendment dated 5-8-02 is acknowledged.**

**Since there are two claims with the number 26, the claims have been renumbered according to rule 126 with the second claim number 26 as 27. Claims included in the prosecution are 1-34.**

### ***Claim Rejections - 35 USC § 112***

**1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

**The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

**2. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

**‘type’ is indefinite; see Ex parte Copenhaver, 109 USPQ 118.**

### ***Double Patenting***

**3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645**

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(Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-12 and 17-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,183,783. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant 'fluid in supercritical state' includes supercritical carbon dioxide recited in the claims of said patent. Instant particle sizes are deemed to be included in the generic composition claims in said patent.

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***Claim Rejections - 35 USC § 102***

**5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless -**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

**6. Claims 1-8, 11-14, 16-21, 25, 27, 31-32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/313,46 of record.**

**WO discloses polymeric micro particles for inhalation. The particles are coated with surfactant such as a phospholipid, DPPC, DPPG for example. The particles contain a variety of active principles such as hormones, both protein and non-protein type (insulin, estrogens), antiasthmotics (albuterol). The particles have density of less than 0.4 g/cm<sup>3</sup> and a mean diameter of 5-30 microns (note pages 8, 9, 10, 20 and 21, Examples 1, 5-11).**

**7. Claims 1-8, 10-13, 17-19, 24, 30, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0706821 of record.**

**EP discloses polymeric micro particles coated with a surfactant (lecithin) prepared by the same method. The particles contain an active principle such as calcitonin. The mean diameter of the particles 20 nm to 100 microns with an apparent density between 0.02 g/cm<sup>3</sup> and 0.8 g/cm<sup>3</sup> (columns, 2, 3, 5, 6, 7, 11, Examples and claims 1, 5,6, 11, 17 and 20).**

**8. Claims 1-12 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 2753639 of record.**

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FR discloses polymeric coated micro particles prepared by the same method using a super critical fluid and an organic solvent. The particles have a diameter of 20 nm to 500 microns with an apparent density between 0.02 g/cm<sup>3</sup> to 0.8 g/cm<sup>3</sup>. The active agents include peptides (note pages 2, 3, 4, 8, Examples and claims 1, 2, 5, 9-14 and 16). US 6,183,783 (of record) appears to be an English equivalent for FR (abstract, col. 3, line 13 through col. 5, line 8; col. 5, line 35 through col. 6, line 53; Examples and claims of US patent).

9. Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/29998.

WO discloses polymeric coated micro particles prepared by the same method using a super critical fluid and an organic solvent (abstract, Examples and claims).

*Claim Rejections - 35 USC § 103*

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 15, 19-20, 22-23, 25-26, 28-29 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/31346 cited above .

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WO's teachings have been discussed above. While WO discloses generic 'phosphoglycerides' and phospholipids, it does not teach claimed individual phosphatidylethanolamine and phosphatidylserine. However, in view of WO's exemplification using phosphatidylcholines and its generic teachings, it is deemed obvious to use any phospholipid with the reasonable expectation of success. WO also does not teach the claimed anti-asthmatic agent, beclametasone. However, in view of WO's teachings of other anti-asthmatic agents such as cromolyn, salmetrol, formeterol and albuterol, it is deemed obvious to one of ordinary skill in the art to use any known anti-asthmatic agent with a reasonable expectation of success.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

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**All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.**

**Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.**



**Gollamudi S. Kishore, Ph. D**

**Primary Examiner**

**Group 1600**

*gsk*

**July 25, 2003**